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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,888	11/12/2003	Daniel G. Dadourian	NCPT-001	2298

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EXAMINER	
BACHMAN, LINDSEY MICHELE	
ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,888	DADOURIAN, DANIEL G.	
	Examiner	Art Unit	
	Lindsey Bachman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 23-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 23-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-24-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Amendment filed on 24 January 2007.

Response to Arguments

1. Applicant's arguments with respect to claims 1-15 and 23-33 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

2. Claims 1, 7, 8, and 12 are objected to because of the following informalities: it is unclear as to whether the interventional device is being claimed as part of the invention. Applicant refers to the interventional device functionally in claim 1, yet in claim 12 the interventional device is considered structurally. Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stop, as described in Claim 32, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 1, 7, 11, 13, 23-31 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Abrams, et al. (US Patent Application 2003/0050684).

7. Claim 1: Abrams'684 discloses a device that contain a sheath (12) having a proximal end (towards 20) and a distal end (towards 26) and a lumen (14) extending between. The sheath is adapted to be affixed to an interventional device. Further, the device contains an ostial locator wire (24) that is slidably disposed within the sheath

(paragraph [0044]). The wire has a distal region that assumes an expanded configuration when extended from the distal end of the sheath that partially encircles the interventional device (paragraph [0043]). The wire has a linear configuration when retracted into the lumen (paragraph [0042]). The sheath is advanceable with the distal region to position the interventional device and removable after delivery (paragraph [0009]).

8. Claim 7: The expanded configuration can be larger than the diameter of the ostium of a branch vessel since vessel vary widely in size.

Claim 11: The tip (distal end of the wire 24) is a lasso that helps retain the expanded configuration centered on the interventional device (see Figures 1, 2, 3).

9. Claim 13: The distal region is capable of assuming a shape in the expanded configuration that is flattened out when the sheath is advanced into an ostium and provide tactical feedback to the user because of the material properties of the wire; namely that it is flexible (paragraph [0051] and [0052]).

10. Claim 23: Abrams'684 discloses an interventional device that is a stent (34) (paragraph [0043]) that is deployable within an ostium (paragraph [0009]). Abrams'684 discloses a sheath (48) having a proximal and distal end and a lumen extending between (see Figure 5). Further, Abrams'684 discloses a an ostial locator wire (24) that is slidably disposed within the sheath (because element 12 is disposed within sheath (34); paragraph [0044]). The wire has a distal region that assumes an expanded configuration when extended from the distal end of the sheath that partially encircles the

interventional device (paragraph [0043]). The wire has a linear configuration when retracted into the lumen (paragraph [0042]).

11. Claim 24: Abrams'684 discloses that the interventional device can contain a balloon and the stent is mounted on the balloon (paragraph [0043]).

12. Claim 25: Further, the device contains an ostial locator wire (24) that is slidably disposed within the sheath (paragraph [0044]). The wire has a distal region that assumes an expanded configuration when extended from the distal end of the sheath that partially encircles the interventional device (paragraph [0043]). The wire has a linear configuration when retracted into the lumen (paragraph [0042]).

13. Claim 26: The distal region is capable of assuming a shape in the expanded configuration that is flattened out when the sheath is advanced into an ostium and provide tactical feedback to the user because of the material properties of the wire; namely that it is flexible (paragraph [0051] and [0052]).

14. Claim 27: The interventional device further contains a catheter (12) for delivering the stent (paragraph [0040]).

15. Claim 28: The catheter (12) is positioned so that the distal end of the sheath is proximal to the stent (see Figure 5).

16. Claim 29: Abrams'684 discloses a device that contains a sheath (12) having a proximal end (towards 20) and a distal end (towards 26) and a lumen (14) extending between. The device also contains an osital locator (24) that is extendable from the lumen of the sheath (paragraph [0044]). The distal region is capable of assuming a shape in the expanded configuration that is flattened out when the sheath is advanced

into an ostium and provide tactical feedback to the user because of the material properties of the wire; namely that it is flexible (paragraph [0051] and [0052]).

17. Claim 30: The distal region is three-dimensional in the expanded configuration before being flattened out (see Figure 1).

18. Claim 31: The expanded configuration of the wire taught by Abrams'684 assumes a coiled arrangement (see Figure 1) that is capable of being flattened out when it reaches an ostium because of the material properties of the wire (paragraph [0051] and [0052]).

19. Claim 33: The device contains a stent (34) (paragraph [0043]). The distal region partially encircles the stent in the expanded configuration and is capable of positioning the stent relative to an ostium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 2-6, 8, 9, 12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams'684.

21. Claim 2: Abrams'684 teaches an embodiment of the delivery device that contains fasteners (50) for fixing the sheath to the interventional device (12) (paragraph [0060]). It would have been obvious to one skilled in the art at the time the invention was made to modify the embodiment of Abrams'684 in Figure 1, with the fasteners taught in the embodiment in Figures 12 and 13, in order to provide a way to attach the interventional device to the sheath in addition to the use of the wire.

22. Claim 3: The fastener can be a thin, flexible sheet that partially wraps around the interventional device (see paragraph [0060]).

23. Claim 4: The fastener is a clasp (50) (paragraph [0060]).

24. Claim 5: The fastener is adapted for being snap fit or friction fit with the interventional device (depending on the dimensions of the interventional device).

25. Claim 6: The clasp is capable of being used with a biocompatible adhesive.

26. Claim 8: The expanded configuration of the wire taught by Abrams'684 assumes a spiral shape (see Figure 1).

27. Claim 9: The expanded configuration of the wire taught by Abrams'684 assumes a coiled arrangement (see Figure 1).

Claim 12: The interventional deice is a stent delivery catheter that includes a stent (34) and the spiral shape partially encircles the stent (paragraph [0043] and Figure 1).

28. Claim 14: The distal most turn of the expanded configuration of the wire is substantially the same as the diameter of the interventional device, which keeps the expanded configuration centered on the interventional device (see Figures 1-4).

29. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams'684, as applied to Claim 1, in further view of Nash, et al. (US Patent 6,524,323).

30. Abrams'684 teaches the limitations of Claim 10 except for an atraumatic tip on the wire.

31. Nash'323 teaches an atraumatic tip (130) on the distal end of a delivery device (124) because it is less likely to damage the vessel. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Abrams'684 with an atraumatic tip taught by Nash'323 because it is less likely to cause damage to the vessel.

32. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams'684, as applied to Claim 1, in further view of Ravenscroft (US Patent 5,702,418).

33. Abrams'684 teaches the limitations of Claim 15 except for a radiopaque feature at the distal end.

34. Ravenscroft'418 teaches a stent delivery system with a distal end (13) that can be made of a radiopaque material in order to visualize the distal end, so that it can be positioned at the correct location when delivering a stent (column 7, lines 42-46). It would have been obvious to one skilled in the art at the time the invention was made to

modify the device taught by Abrams'684 with the radiopaque material taught by Ravenscroft'684 in order to aid in visualizing the device while delivering a stent.

35. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams'684, as applied to Claim 29, in further view of Strecker (US Patent 5,653,748).

36. Abrams'684 teaches the limitations of Claim 32 except for a stop that prevents the ostial locator wire from being extended too far from the sheath.

37. Strecker'748 teaches a stop (43) that holds a wire that surrounds a stent and prevents it from being released (column 7, lines 42-58). It would have been obvious to one skilled in the art at the time of the invention to modify the device taught by Abrams'684 with a stop as taught by Strecker'748 in order to prevent the wire from being released in the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER